Remarks

In the Office Action of July 1, 2003, claims 83-85 were rejected under 35 USC §112, second paragraph, as being indefinite. Specifically, the claims were rejected since it was unclear what the term "by weight" referred to—the soy protein material or the overall composition. Applicants respectfully traverse the rejection. Applicants have amended claims 83-85 to indicate that the term "by weight" refers to the weight of the soy protein material. Applicants respectfully direct the Examiner's attention to U.S. Patent No. 6,544,566 where claims having substantially identical syntax with the presently amended claims were allowed to grant. Applicants submit, therefore, that the amended claims 83-85 are not indefinite under 35 USC §112, second paragraph and that the amendment places the claims in better condition for allowance and appeal and should be entered in the file of the application.

In the Office Action of July 1, 2003, claims 79-85 were rejected under 35 USC §102(b) as anticipated by EP 0 380 343. Applicants respectfully traverse the rejection.

Claim 79 and its dependent claims 80-86 provide a composition comprising a soy protein material with at most 4000 mg/kg of ribonucleic acids. Claim 81 provides the composition of claim 79 wherein the soy protein material contains at most 2000 mg/kg of ribonucleic acids, and claim 82 provides the composition of claim 79 wherein the soy protein material contains at most 1500 mg/kg of ribonucleic acids. The claimed levels of ribonucleic acids are significantly less than the levels of ribonucleic acids present in soy protein materials that have not been treated to degrade ribonucleic acids, where the ribonucleic acid content typically ranges from 16,000 mg/kg to 23,000 mg/kg.

EP 0 380 343 A2 (the "'343 patent) teaches a method for production of phytate-free or low-phytate soy protein isolates or soy protein concentrates. The '343 patent is directed to a method of degrading phytates with one or more phytate-degrading enzymes, where acid phosphatases are disclosed as one type of phytate-degrading enzyme. The '343 patent does not disclose or mention ribonucleic acids at all, and clearly does not provide for a soy protein material containing any specified levels of ribonucleic acids.

Claim 79 and its dependent claims are not explicitly anticipated by the '343 patent since the '343 patent does not disclose ribonucleic acids at all, and clearly does not teach a soy protein material containing at most 4000 mg/kg ribonucleic acids. Therefore, the

only possible basis for anticipation is that the claims are inherently anticipated by the '343 patent.

Claim 79 and its dependent claims, however, are not inherently anticipated by the '343 patent since the process disclosed by the '343 patent does not necessarily result in a soy protein material containing at most 4000 mg/kg ribonucleic acids. Anticipation by inherency applies when a claimed element is "always present" and "naturally flows" from the prior art disclosure. Inherency may not be established by probabilities or possibilites—the mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981). More particularly, for a claim element to be anticipated inherently by a reference the element must be a necessary consequence of what was deliberately intended as disclosed in the prior art reference. *Mehl/Biophile International Corp. v. Milgraum*, 52 USPQ2d 1303, 1307 (CAFC 1999). Occasional results are not inherent. *Id.* at 1306. See also *Trintec Industries Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597, 1599 (CAFC 2002); *In Re Robertson*, 49 USPQ2d 1949, 1950-51 (CAFC 1999); *Rosco Inc. v. Mirror Lite Co.*, 64 USPQ2d 1676, 1679-81 (CAFC 2002); and *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ2d 1746, 1748-1750 (CAFC 1991).

The Office Action clearly shows that the basis for the §102(b) rejection with respect to the claimed RNA levels is that "the low amounts of RNAs are inherent to the cited disclosure because RNA is present in the soy protein, thus the claimed ranges are inherent in the soy protein isolate of the cited reference" (Office Action, page 4, lines 5-7). As noted above, however, soy protein materials typically contain significantly greater levels of RNA than the claimed soy protein material that contains at most 4000 mg/kg RNA. Specifically, soy protein materials that have not been treated to degrade RNA typically contain from 16,000 to 23,000 mg/kg RNA.

The reference is directed to reducing phytate, not RNA, in a soy protein material. Specifically, on page 6, lines 38-41 the EP 0 380 343 A2 reference states:

> Stated most simply, in its broadest terms the present invention comprises:
>
> (a) suspending defatted soy bean particulate in an aqueous medium in the presence of an enzyme preparation comprising one or more phytate-degrading enzymes (emphasis added): and
>
> (b) isolating the resulting phytate-free or low phytate soy protein.

The reference explains what phytate-degrading enzymes are, with respect to the invention of the reference (page 6, lines 16-27):

> In the various aspects of the present invention, phytic acid is eliminated by means of effective commercially available bulk enzyme compositions. Phytate-degrading enzymes dephosphorylate inositol-hexaphosphate to yield inositol and orthophosphate, several forms of inositolphosphates being the intermediate products. Phytate degrading enzymes include phytase and acid phosphatases.
>
> Phytase and acid phosphatases are produced by various microorganisms such as Aspergillus spp., Rhizopus spp., and yeasts (Appl. Microbiol. 16: 1348-1357 (1968 Enzyme Microb. Technol. 5: 377-382 (1983)), and phytase is also produced by various plant seeds, for example wheat, during germination. According to methods known in the art, enzyme preparations can be obtained from the above mentioned organisms. Caransa et al. Netherlands Pat. Appl. 87.02735, found that at the same enzyme dosage phytase from Aspergillus spp. degraded phytic acid in corn more efficiently than phytase from wheat.
>
> Particularly preferred for the purposes of the present invention are the Finase enzymes, formerly termed Econase EP 43 enzymes (emphasis added), manufactured by Alko Ltd., Rajamaki, Finland.

The phytate-degrading enzymes of the reference do not necessarily degrade ribonucleic acids in a soy protein material, and do not necessarily produce a soy protein material containing at most 4000 mg/kg RNA when a soy protein material is treated with such enzymes. For example, NAUTUPHOS® is an enzyme preparation that is commercially sold as a phytase (*see* Exhibit A attached hereto) that does not degrade ribonucleic acid in a soy protein material to produce a soy protein material containing at most 4000 mg/kg of ribonucleic acids in accordance with the current claims (*see* Exhibit B attached hereto). NATUPHOS® clearly falls within the description of an enzyme preparation useful in the process of the reference since it degrades phytates and phytic acid in a soy protein material when utilized in accordance with the disclosed process (*see* Exhibit B).

Therefore, the deliberate intent of the cited reference, to degrade phytates and phytic acid in a soy protein material with a phytate-degrading enzyme preparation, can be achieved utilizing enzyme preparations that do not degrade ribonucleic acids (e.g. NATUPHOS® enzyme). As such, the claimed composition—a soy protein material containing at most 4000 mg/kg of ribonucleic acids—is not a necessary consequence of the deliberate intent of the cited reference, and the cited reference cannot inherently anticipate the claims of the present application.

Furthermore, even though the reference discloses the use of acid phosphatase enzymes as one of many enzymes effective to degrade phytates and phytic acid in a soy

protein material according to the process of the reference, production of a soy protein material containing at most 4000 mg/kg RNA (claim 79) is not a necessary consequence of the use of an acid phosphatase as disclosed in the reference. For example, a soy protein material produced by the process of the reference where an acid phosphatase enzyme is utilized in the process will contain less RNA than the soy protein material did prior to the process, however, the soy protein material may contain more than 4000 mg/kg. In the same manner, the reference does not inherently teach a soy protein material containing less than 2000 mg/kg ribonucleic acids (claim 81) or a soy protein material containing less than 1500 mg/kg (claim 82).

In summary, the cited reference does not provide a soy protein material that inherently contains low amounts of RNA because 1) the process disclosed by the reference can be practiced with an enzyme preparation that does not degrade RNA in a soy protein material (ie. a soy protein material containing less than 4000 mg/kg RNA is not a necessary consequence of the process of the reference); and 2) even if the process of the reference is practiced with an enzyme preparation that can degrade RNA, production of a soy protein material containing at most 4000 mg/kg RNA or less than 2000 mg/kg RNA or less than 1500 mg/kg RNA is not a necessary consequence of the process (e.g. the process could produce a soy protein material containing 4500 mg/kg RNA or more).

In the Office Action of July 1, 2003, claims 79-86 were rejected under 35 USC §103(a) as being obvious over EP 0 380 343.

Claim 1 and its dependent claims 3-36 were rejected as obvious over the '343 patent since allegedly any difference between the claims and the '343 patent is considered to be so slight as to render the claims *prima facie* obvious over the '343 patent. As noted above, however, the '343 patent provides no disclosure at all relating to degrading ribonucleic acids. One skilled in the art would learn absolutely nothing about how to produce a soy protein material composition having low RNA levels from the '343 patent, and thus one skilled in the art would never look to the '343 patent for any guidance in determining how to produce a soy protein material composition having at most 4000 mg/kg of RNA. Therefore, no basis whatsoever has been established for a case of *prima facie* obviousness based on the disclosure of the '343 patent.

The Office Action states that "it would have been obvious to one of skill in the art at the time of the claimed invention was made to degrade ribonucleic acids along with phytic acid because of enzymatic activity of Finase which can degrade phytate as well as can be expected to degrade RNAs" (emphasis added). No proof is provided by the Patent Office to show that one skilled in the art would expect Finase to degrade RNAs as of the time of the claimed invention. In fact, it appears the Examiner is retroactively viewing the disclosure of the reference through the lens of the invention; improper hindsight that cannot be used to establish a *prima facie* case of obviousness. (*See* In re Decbiczak, 50 USPQ2d 1614 (Fed. Cir. 1999)—obviousness must be determined as of "the time of the invention" to avoid the "tempting but forbidden zone of hindsight"). Therefore, no *prima facie* case of obviousness has been established from the '343 patent reference since it is clear that one skilled in the art would find nothing related to soy protein materials containing significantly reduced levels of RNA in the disclosure of the '343 patent; and no other evidence has been provided to support the assertion that one skilled in the art would have been aware that soy protein materials containing reduced levels of RNA could be produced by acid phosphatase enzymes reacting with a soy protein material.

In the Office Action of July 1, 2003 claims 79 and 86 were rejected under 35 USC §103(a) as being unpatentable over EP 0 380 343 in view of U.S. Patent No. 6,313,328 to Ulrich et al. Applicants respectfully traverse the rejection.

Ulrich et al discloses a method of extraction of corn oil from flaked corn grain. The corn oil may be extracted from corn grain using extracting equipment used for extracting oil from soy flakes. The phosphorus content of the corn oil in Example 1 is 365 ppm. EP 0 380 343 is discussed above.

Claim 79 is discussed above. Claim 86 provides the composition of claim 79 in which the soy protein material contains less than 3000 ppm phosphorus.

There is no suggestion to combine the cited references to arrive at the presently claimed invention. Case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g.,* C.R. Bard, Inc. v. M3 Sys., Inc., 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential

evidentiary component of an obviousness holding"); In re Rouffet, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); In re Fritch, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); In re Fine, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also* Graham, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g.*, Interconnect Planning Corp. v. Feil, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.").

One skilled in the art would have no reason to combine the teachings of the '343 patent and Ulrich et al. The '343 patent is directed to producing a soy protein material containing reduced levels of phytates and phytic acid. The soy protein material is a soy protein isolate or a soy protein concentrate—soy protein materials that are produced from defatted soy flakes (see Soy Protein Products, page 3 first 3 paragraphs, page 4, and page 5, Table 1, Exhibit C attached hereto). In the art of soy processing "defatting" is equivalent to "deoiling", therefore, the soy protein concentrates and soy protein isolates utilized in the process of the '343 patent have had oil removed therefrom. Ulrich is directed to a method for obtaining a corn oil.

One skilled in the art would have no reason to combine the teachings of the references because: 1) one reference refers to a method for processing a soy material and the other reference refers to a method for processing a corn material, and soy and corn processing are substantially different; 2) one reference refers to a method for processing a substantially oil-free material to produce a substantially oil-free product and the other

reference refers to a method for extracting oil from an oil containing material to form an oil product; and 3) the disclosed processes are so different that there is no teaching in one reference that is applicable in the method of the other reference.

Furthermore, even if the references could be combined, the combined references have little to do with the claimed compositions. The claimed compositions are directed to a soy protein material containing at most 4000 mg/kg of RNA. Neither of the references discloses RNA at all, therefore, one skilled in the art would find no teaching leading to the claimed compositions of claims 79 and 86. Further, claim 86 is directed to a soy protein material containing at most 4000 mg/kg RNA where the soy protein material contains less than 3000 ppm phosphorus. Ulrich et al disclose a corn oil containing less than 3000 ppm phosphorus, but it is unclear how that would teach a person skilled in the art to produce a soy protein material containing less than 3000 ppm phosphorus.

In light of all the above, Applicants respectfully request allowance of the remaining claims 79-86.

Respectfully submitted,

WONG ET AL

Date 8/6/03

By: _____

Richard Taylor Reg. No. 37,248
Lead Patent Counsel
Solae, LLC
(314) 982-3004

EXHIBIT A

BASF Aktiengesellschaft BASF

The natural key to higher yields

natuphos®

The original phytase

Natuphos® offers the following benefits:

- Improvement of phosphorus digestibility in pig and poultry diets
- Quantified improvement of nutrient digestibility and energetic value of feed
- Saving of feed costs due to reduction of expensive feed ingredients in the feed formula
- Reduced excretion of phosphorus (over 30 % less)
- Outstanding bioefficacy

Our current product portfolio comprises:

- Natuphos®
- Natugrain®
- Natuphos Combi®
- Natustarch®
- Screensaver
- BASF Aktiengesellschaft
- DSM

Natuphos® is available in a wide range of product formulations, providing powder, granule or liquid products of different phytase concentrations:
Natuphos® 5000
Natuphos® 5000 G
Natuphos® 5000 L
Natuphos® 10000 G*
Natuphos® 10000 L*

The original phytase
The development of Natuphos® was prompted by environmental problems in regions with high livestock density. Its microbial 3-phytase, obtained from *Aspergillus niger*, releases phosphorus from phytate, the storage form of phosphorus in vegetable feed compounds, which is more or less undigestible to pigs and poultry.
Thus, supplementation of feed with Natuphos® markedly increases the availability of phosphorus but also of other phytate-bound minerals and nutrients. Released from phytate, these nutrients can be efficiently used by the animal instead of being lost with the manure.

Reliable efficiency
The use of Natuphos® ensures a maximum release of digestible phosphorus from vegetable feedstuffs per phytase unit. Numerous feeding trials have shown the superior bioefficacy of Natuphos® compared to competitor products based on *Peniophora lycii* phytase. The mean exchange rate of Natuphos® versus Peniophora phytase in liquid products amounts to 1:1.5, in granular products it is at least 1:2.

Less phosphorus in the manure
Since Natuphos® improves phosphorus digestibility, feed supplementation with inorganic phosphorus can be reduced. In this way, Natuphos® decreases the excretion of phosphorus by over 30 %, providing ecological and economical benefits.

Feed optimisation with Natuphos®
Based on the results of numerous feeding trials, nutrient equivalencies have been

developed for Natuphos®. These figures express the extent to which nutrients are released by Natuphos® from phytate in the feed. They can be used in the same way as analysed nutrient contents of feed compounds to optimise least cost formulas. Feed optimisations reveal the economic advantages which can be gained by supplementing rations with Natuphos®.

Natuphos® formulations
Different formulations and concentrations of Natuphos® help to meet the customers' individual requirements for the manufacturing of quality feed under different production conditions:

POWDER
Natuphos® 5000:
fine, yellowish brown powder, recommended for use in non-pelleted compound feed and feed pelleted below 75°C
min. 5.000 FTU/g phytase activity

GRANULES
Natuphos® 5000 G:
fine white granules, recommended for use in compound feed pelleted up to 85°C
min. 5.000 FTU/g phytase activity
Natuphos® 10000 G*:
highly concentrated, fine white granules, recommended for use in concentrated premixes and in compound feed pelleted up to 85°C
min. 10.000 FTU/g phytase activity

LIQUIDS
Natuphos® 5000 L:
yellowish brown liquid, recommended for use in compound feed pelleted above 85°C (post pelleting application)
min. 5.000 FTU/g phytase activity
Natuphos® 10000 L*:
highly concentrated, yellowish brown liquid, recommended for use in compound feed pelleted above 85°C (post pelleting application)
min. 10.000 FTU/g phytase activity

*Available only outside the European Union

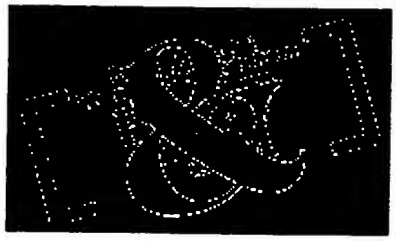

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EXHIBIT B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	: Deborah K. Ware
Group Art Unit:	: 1651
Applicants	: Wong et al.
Serial No.	: 09/912,494
Filed	: July 24, 2001
For	: METHOD FOR PRODUCING ULTRAPURE PROTEIN MATERIALS

Hon. Commissioner of Patents and Trademarks
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION UNDER 37 CFR §1.132

Theodore M. Wong declares as follows:

1. I am an inventor of the subject matter of the above identified patent application.

2. I received a Bachelor of Arts Degree in Biology from Greensboro College in May, 1974, a Masters Degree in Microbiology from the University of Texas at Arlington in May 1976 and a Ph.D. Degree in Food Science/Food Biochemistry from Louisiana State University in May, 1982.

3. I have been employed by Solae, LLC, previously known as Protein Technologies International, Inc., since August 19, 1985, and currently hold the position of Senior Research Director, Product Development R&D.

4. Under my direction and control an experiment was conducted to determine the extent of degradation of phospho- and diphospho-ester nucleoside containing compounds in a soy protein material by an acid phosphatase enzyme preparation in comparison with NATUPHOS® phytase enzyme. Three samples of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample ("Control"), the second sample was dosed with an acid phosphatase enzyme preparation having an enzyme activity of 1400 KPU per Kg curd solids ("Acid Phosphatase") and the third sample was dosed with NATUPHOS® phytase

enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids ("Natuphos"). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then treated with bacterial alkaline phosphatase to degrade monomeric nucleotides to monomeric nucleosides and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provides a measure of the amount of monomeric nucleotides and monomeric nucleosides present in the sample ("Monomerics"). Another sample of each of the three samples was treated with a nuclease to hydrolyze polymeric ribonucleic acids to monomeric nucleotides, then was treated with pyrophosphatase to hydrolyze ribonucleoside containing adducts to monomeric nucleotides, then was treated with bacterial alkaline phospatase to hydrolyze the monomeric nucleotides to free monomeric nucleosides, and then the free monomeric nucleoside content of the treated samples was measured. The resulting free monomeric nucleoside content provides a measure of the total amount of ribonucleoside containing compounds, both polymeric and monomeric, since the nuclease and pyrophosphatase treatments degrade the polymeric ribonucleoside-containing compounds to monomeric nucleotides, which are subsequently degraded to monomeric nucleosides with bacterial alkaline phosphatase ("Total"). The resulting ribonucleoside content by weight of nucleosides for each sample is shown in Table 1.

TABLE 1

Sample	Uridine	Cytidine	Guanosine	Adenosine	Total
Control					
--Monomerics	172	121	237	127	657
--Total	4302	5320	6711	5886	22219
Acid Phosphatase					
--Monomerics	5188	6886	7175	2204	21453
--Total	5281	7015	7599	2495	22390
Natuphos					
--Monomerics	231	128	240	184	783
--Total	4542	5628	6866	6070	23106

Table 1 shows that treatment with the acid phosphatase enzyme preparation produced a soy material product in which 95.8% [(21453/22390)*100] of all ribonucleoside containing compounds were either in their monomeric nucleoside form or their monomeric nucleotide form—clearly indicating the degradation of most polymeric ribonucleic acids in the soy material. Table 1 also shows that treatment with the NATUPHOS® phytase enzyme produced a soy material product in which 3.3% [(783/23106)*100] of all ribonucleoside containing products were either in their monomeric nucleoside form or their monomeric nucleotide form. The NATUPHOS® phytase enzyme degraded little or no polymeric ribonucleic acids, as can be shown by comparing amount of monomeric nucleosides and monomeric nucleotides in the soy material treated with NATUPHOS® to the Control, which contained 3.0% [(657/22219)*100] of all ribonucleoside containing products as monomeric nucleosides or monomeric nucleotides. NATUPHOS®, therefore, clearly did not degrade substantial amounts of ribonucleic acids to monomeric nucleosides or monomeric nucleotides, while the acid phosphatase enzyme preparation degraded almost all polymeric ribonucleoside-containing compounds to monomeric nucleosides and monomeric nucleotides.

5. Under my direction and control an experiment was conducted to determine the extent of degradation of phytic acid in a soy protein material by an acid phosphatase enzyme preparation in comparison with NATUPHOS® phytase enzyme. Three samples of soy protein curd at pH 4.6 were prepared. The first sample was used as a control sample ("Control"), the second sample was dosed with an acid phosphatase enzyme preparation having an enzyme activity of 1400 KPU per Kg curd solid ("Acid Phosphatase") and the third sample was dosed with NATUPHOS® phytase enzyme preparation having an enzyme activity of 1800 FTU per Kg curd solids ("Natuphos"). After dosing the second and third samples with their respective enzyme preparations, the three samples were heated to 50°C for two hours. A sample of each of the three samples was then analyzed to

determine phytic acid content, by weight percent of the soy protein material. The results are shown in Table 2.

TABLE 2

Sample	Phytic Acid (wt. %)
Control	1.46
Acid Phosphatase	0.12
Natuphos	0.11

Table 2 shows that both NATUPHOS® and the acid phosphatase enzyme preparation were effective to degrade phytic acid in a soy protein material relative to a soy protein material not treated with either enzyme. Tables 1 and 2, together, show that NATUPHOS® is effective to degrade phytic acid but not polymeric ribonucleoside-containing compounds such as ribonucleic acid, while an acid phosphatase enzyme preparation is effective to degrade both phytic acid and polymeric ribonucleoside-containing compounds such as ribonucleic acid.

Theodore M. Wong

Date: August 4, 2003

EXHIBIT C

SOY PROTEIN PRODUCTS

CHARACTERISTICS, NUTRITIONAL ASPECTS AND UTILIZATION

Published by the Soy Protein Council,
1255 Twenty-Third Street, NW
Washington, DC 20037
(202) 467-6610

SOY PROTEIN PRODUCTS/SPC

II. Definitions And Methods Of Preparation

The soybean plant (*Glycine max*) belongs to the legume family. It is able to utilize the nitrogen of the air through the action of bacteria on its roots. The protein content of the seed is about 40%. After the hulls and the oil are removed, the remaining defatted flake, which is the starting material for most commercial protein ingredients, has a protein content of approximately 50%.

Soybeans entering the processing plant are screened to remove damaged beans and foreign materials, then treated as shown in Figure 1. The oil is removed from the flakes by a solvent (hexane) in one of several types of countercurrent extraction systems. After the defatted flakes leave the extractor, any residual solvent is removed by heat and vacuum.

Soy protein products fall into three major groups. These groups are based on protein content, and range from 40% to over 90%. All three basic soy protein product groups (except full-fat flours) are derived from defatted flakes. They are: soy flours and grits, soy protein concentrates and soy protein isolates (Table 1).

There are also specialty products based on traditional Oriental processes, which utilize the entire bean as starting material.

Soy Flours and Grits

Soy flours and grits are made by grinding and screening soybean flakes either before or after removal of the oil. Their protein content is in the range of 40% to 54%.

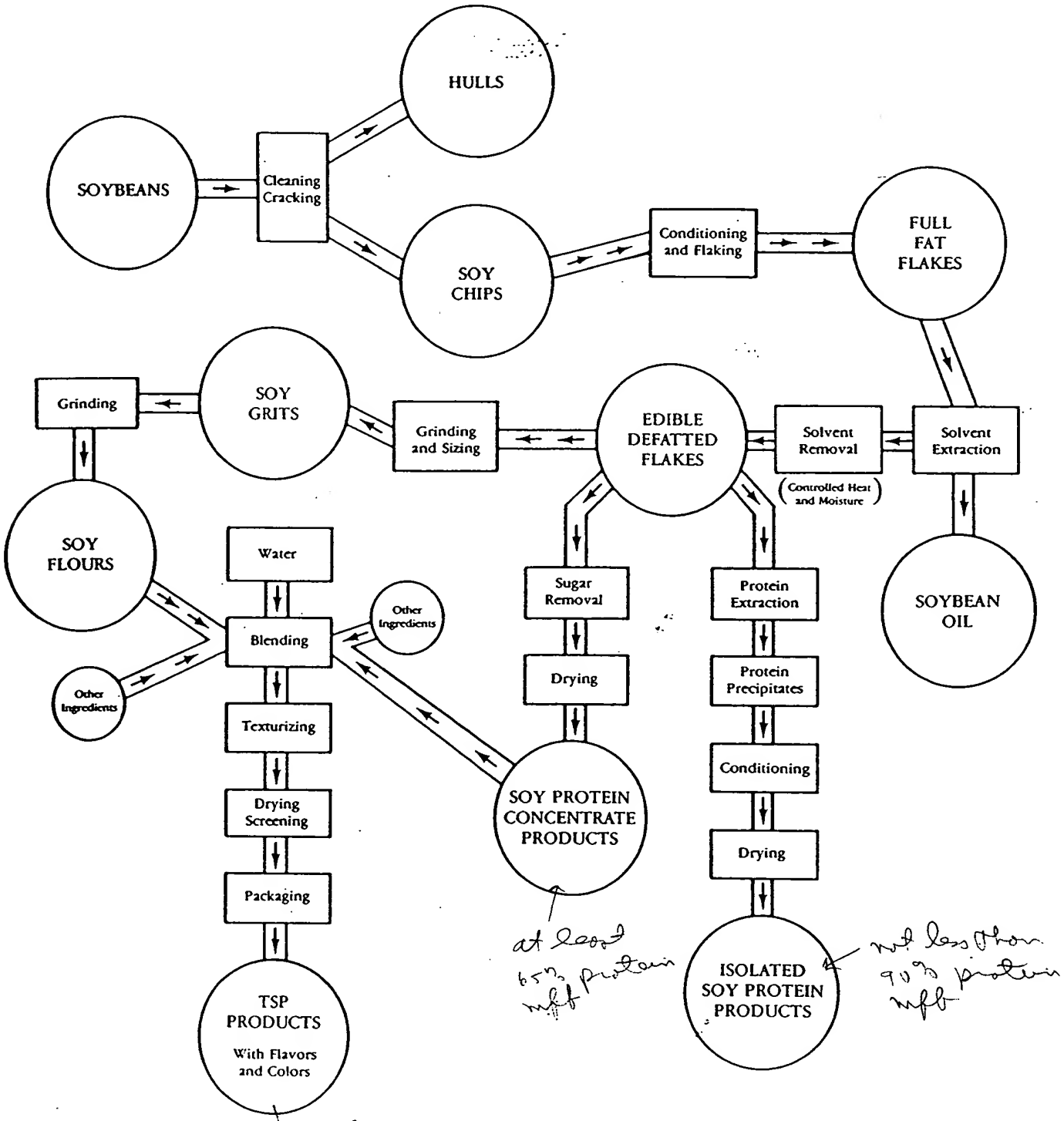
Soy flours and grits are the least refined forms of soy protein products used for human consumption and may vary in fat content, particle size, and degree of heat treatment. They are also produced in lecithinated or refatted forms. The degree of heat treatment creates varying levels of water dispersibility, a quality that can be useful in tailoring functionality in many food applications. Preparation and uses of various flours are as follows:

Type	Preparation	Uses
Full-fat flours (40% protein*)	Dehulled cotyledons are milled to specific size.	Produced primarily in Europe and Asia for the baking industry and the production of soy milks.
High enzyme flours (52% to 54% protein*)	Produced from defatted flakes with minimum heat. High NSI**	Increasing mixing tolerance and bleaching in bread; preparation of functional concentrates and isolates.
Defatted flours (52% to 54% protein*)	Finely ground to pass through a No. 100 U.S. Standard Screen size. Controlled moist heat treatment used to provide 'white' (NSI 85 to 90), 'cooked' (NSI 20 to 60), and 'toasted' (NSI below 20) grades.	Varied uses requiring a wide range of protein solubilities.
Defatted grits (52% to 54% protein)	Screen size between No. 10 and 80. Otherwise the same as flours.	Ground meat systems and bakery products.
Lecithinated/ Refatted flours	Lecithin or vegetable oil is combined with defatted flakes (0.5% to 30%).	Improving water dispersibility and emulsifying capability in baking applications.

(*) N×6.25
(**) Nitrogen Solubility Index (NSI), as is basis

Figure 1.

SOY PROTEIN PROCESSING



mfb: moisture free basis

TABLE 1.
COMPOSITION OF SOY PROTEIN PRODUCTS

	Defatted Flours & Grits		Concentrates		Isolates	
Constituent	as is	mfb*	as is	mfb*	as is	mfb*
Protein (N×6.25)	52–54	56–59	62–69	65–72	86–87	90–92
Fat (pet. ether)	0.5–1.0	0.5–1.1	0.5–1.0	0.5–1.0	0.5–1.0	0.5–1.0
Crude Fiber	2.5–3.5	2.7–3.8	3.4–4.8	3.5–5.0	0.1–0.2	0.1–0.2
Ash	5.0–6.0	5.4–6.5	3.8–6.2	4.0–6.5	3.8–4.8	4.0–5.0
Moisture	6%–8%	0	4%–6%	0	4%—6%	0
Carbohydrates (by Difference)	30–32	32–34	19–21	20–22	3–4	3–4

*mfb: moisture free basis

SOY PROTEIN CONCENTRATES

Soy protein concentrates are prepared from dehulled and defatted soybeans by removing most of the water-soluble, non-protein constituents as summarized in the following column. They contain at least 65% protein (N×6.25) on a moisture-free basis (mfb).

Type	Preparation	Uses
Soy Protein Concentrates	Produced by three basic processes: acid leaching (at about pH 4.5), extraction with aqueous alcohol (70% to 90%), and denaturing the protein with moist heat prior to extraction with water.	Varied applications requiring low-flavor profile, water and fat absorption, and emulsification (dispersible form). Nutritional applications.

Neutralized concentrates prepared by acid leaching have a higher water-soluble protein content than those prepared by either alcohol leaching or heat denaturation techniques. In a more recently developed process, a low water-soluble soy protein concentrate (aqueous alcohol extraction) is subjected to heat treatment by steam injection or jet cooking to increase solubility and functionality. Functionality may be improved further by additional treatment in a homogenizer. These concentrates function as emulsifiers and emulsion stabilizers, they bind fat and water, and they offer special adhesive properties similar to those of isolates.

SOY PROTEIN ISOLATES

Isolates are the most highly refined soy protein products commercially available. They represent the major proteinaceous fraction of the soybean. Soy isolates are prepared from dehulled and defatted soybeans by removing most of the non-protein components as summarized in the accompanying chart. They contain not less than 90% protein (N×6.25) on a moisture-free basis.

Isolates may also be lecithinated to improve dispersibility and to reduce dusting. Both gelling and non-gelling varieties are available, as well as varying grades of viscosity.

Type	Preparation	Uses
Soy Protein Isolates (Isoelectric and Neutralized)	The protein is extracted from defatted soybean flakes with water or mild alkali in a pH range of 8 to 9 followed by centrifuging to remove insoluble fibrous residue; adjusting resulting extract to pH 4.5 where most of the protein precipitates as a curd; separating curd by centrifugation from the soluble oligosaccharides, followed by multiple washings, and then spray-drying to yield an 'isoelectric' isolate.	Infant formulas and nutritional applications.
	More commonly, the isolate is neutralized (Na or K proteinates) to make it more soluble and functional. About one third of starting flake weight is recovered in the form of an isolate.	Meat and dairy products. Varied applications requiring emulsification/emulsion stabilization; water and fat absorption; adhesive/fiber forming properties. Food analogs.

Textured Soy Proteins

Textured soy proteins (TSP) are processed to impart a structure, such as fiber or chunk, for use as a food ingredient. They are frequently made to resemble meat, seafood or poultry in structure and appearance when hydrated. Their preparation and uses are as follows:

Type	Preparation	Uses
Textured Flours and Concentrates	Thermoplastic extrusion or steam texturization of soy flours or alcohol/heat denatured concentrates. Composition is similar to the corresponding source material.	Many types of fibrous foods, ground meat products, poultry and seafoods.
Structured Concentrates	Processing through an extruder into different sizes and shapes.	Poultry, meats and seafoods.
Structured Isolates	Extrusion as above or by extruding a solution of the isolate into an acid-salt bath that coagulates the protein into fibers that are combined with binders to form fiber bundles.	Poultry and seafoods. Food analogs.

Specialty Soy Foods and Ingredients

Partially hydrolyzed soy protein products are products obtained by cleavage of the protein by proteolytic enzymes, such as pepsin, papain, and bromelain to reduce the molecular weights of proteins to a range of 3,000 to 5,000. This improves whipping properties and acid solubility.

Fully hydrolyzed proteins used as flavoring agents can be prepared from soy grits by acid hydrolysis. A number of enzyme hydrolysates are also available as flavoring agents.

Oriental soy foods, both fermented and nonfermented products, are part of the daily diet in many areas of the world. Products such as soy sauce (shoyu), tofu, tempeh, and others are becoming more popular in the United States and Europe. Preparation and uses of these soy foods are as follows:

Type	Preparation	Uses
Soy Milk	Aqueous extract of the whole soybean.	Same as cow's milk.
Tofu (soy curd)	Made by coagulation of soy milk. Tofu curd contains 88% moisture, 6% protein, and 3.5% oil. Tofu can also be frozen, aged and dried (56% protein).	Same as milk and cheese. Fresh dried (kori) tofu has a shelf life of six to 12 months.
Tempeh	Composed of cooked soybeans fermented by the mold *Rhizopus oryzae* (protein content about 20% on a wet basis and 50% after drying).	Indonesian dish.
Miso (soy paste)	Made by fermentation of cooked soybeans with the mold *Aspergillus oryzae* grown on rice or barley.	Soup base and condiment.
Soy Sauce	Made by fermentation of a combination of soybeans and cereals, usually wheat.	Flavoring agent.
HVP (hydrolyzed vegetable protein)	Acid and/or enzyme hydrolysis of soy grits.	Flavoring agent.
Whipping Protein	Partial hydrolysis with enzymes.	Whipped proteins.